Exhibit 5

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, vs. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH, AND HOFFMANN-LA ROCHE INC., Defendants	)	CIVIL ACTION No.: 05-CV-12237WGY

DEFENDANTS' MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION AND FAILURE TO STATE A CLAIM FOR WHICH RELIEF MAY BE GRANTED

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I. PRELIMINARY STATEMENT

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively, "Roche"), respectfully submit this memorandum in support of Defendants' Motion to Dismiss the Complaint of Plaintiff Amgen Inc. ("Amgen") pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) for Lack of Subject Matter Jurisdiction and for Failure to State a Claim for Which Relief May be Granted.[1] Fundamentally, Roche's motion should be granted because there is no claim of current infringement in view of 35 U.S.C. § 271(e)(1), and suggestions of future infringement are simply too remote and speculative to be actionable.

First, all of Roche's current activities are protected from infringement under the "safe harbor" provisions of 35 U.S.C. § 271(e)(1). As a result, Roche maintains a complete statutory defense to patent infringement. Amgen tacitly concedes as much, since its only cause of action is limited to declaratory judgment of infringement. There is no cause of action for current infringement.

Second, any alleged future conduct that may fall outside section 271(e)(1) is too remote and speculative to give rise to the actual case or controversy requirement of a declaratory judgment action. An application to market and sell its currently unmarketed product, Continuous Erythropoiesis Receptor Activator ("CERA"), will be filed with the U.S. Food and Drug Administration ("FDA") in 2006. If everything proceeds smoothly, and CERA's application follows the average time for new drug approval in recent years, it will take about 22-25 months for CERA to gain approval. As with all drugs, approval time could be more or less. When

[1] Defendants F. Hoffmann-La Roche Ltd and Roche Diagnostics GmbH have simultaneously and separately moved to dismiss this action against them for lack of personal jurisdiction. Nothing contained herein is intended to be, nor should be, taken as a concession that personal jurisdiction over these parties in this matter is proper.

weighed against the timing and uncertainty of FDA approval, the laundry list of "preparatory" activities alleged by Amgen does not establish the existence of an "imminent threat" sufficient to establish a present and actual controversy. Therefore, as a matter of law, this declaratory judgment action should be dismissed for lack of jurisdiction.

Finally, even if the Court finds that declaratory judgment jurisdiction exists, the Court should decline to exercise jurisdiction and dismiss this action. Retaining jurisdiction at this time undermines the purpose of the safe harbor provision of section 271(e)(1). Through years of painstaking research, Roche developed an ingenious new drug, CERA, for stimulating red blood cell production to treat anemia in kidney-impaired and cancer patients. CERA is currently undergoing clinical trials, and Roche is in the process of preparing to file an application to market and sell CERA. Section 271(e)(1) would be totally ineffectual in preventing the expensive, premature, resource-draining litigation that it is designed to prevent if a patentee can get around it by simply filing a declaratory judgment action based solely on the fact that defendant has sought FDA approval for its product and undertaken actions to facilitate that approval. If CERA is approved by the FDA, it will compete with Amgen's anemia drugs. In fact, the timing and venue chosen by Amgen reveal that it was not an "imminent threat" that motivated this lawsuit, but fear of competition and forum shopping. This case was filed in a forum where Roche has no offices, employees or significant contacts, apparently based solely on prior litigation success involving the same patents, and not due to any connection between this district and the allegations in the complaint, right before Roche was rumored to be preparing to present initial Phase 3 clinical results for CERA at a widely attended nephrology meeting.

Roche did not present the rumored results, but it did present promising Phase 2 data for CERA at that meeting. Subsequently, Roche has announced certain Phase 3 results. However,

the simple fact remains that CERA is not approved for commercial sale in the United States and its uses here are solely for the purpose of obtaining FDA approval. At the appropriate time, if and when CERA is approved by the FDA, and assuming that Amgen persists in making its unfounded assertions that CERA infringes its patents, Roche will demonstrate that Amgen is wrong. Until that time, Amgen should not be permitted to interfere with Roche's goal of seeking FDA approval for a superior therapeutic product to be used in treating patients suffering from anemia.

II. BACKGROUND

A. Erythropoietin

As this court is well aware, erythropoietin is a naturally occurring hormone that stimulates red blood cell production as well as the division and differentiation of progenitor cells in the bone marrow. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 214 (D. Mass. 2004) (Young, C.J.). Knowledge of the existence of erythropoietin, of its production by the kidney, and of its functions and beneficial attributes has been widely available for decades. Hoechst, 339 F. Supp. 2d at 214.[2] Several years after its purification from human urine in 1977, the human erythropoietin gene was isolated, sequenced and cloned, enabling the expression of recombinant human erythropoietin("rHuEPO"). Id.[3]

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[2] See also MaryAnn Foote, Studies of Erythropoiesis and the Discovery and Cloning of Recombinant Human Erythropoietin, in ERYTHROPOIETINS AND ERYTHROPOIESIS 15 G. Molineux et al., Eds. (Birkhäuser Verlag, 2003).

[3] See also K. Jacobs, et al., Isolation and Characterization of Genomic and cDNA Clones of Human Erythropoietin, 313 Nature 806 (1985); Fu-Kuen Lin, et al., Cloning and Expression of the Human Erythropoietin Gene, 82 Proceedings of the National Academy of Sciences of the United States of America 7580 (1985).

Because of its ability to stimulate red blood cell production, rHuEPO is widely used to treat anemia due to kidney disease and cancer therapy. Since 1989, Amgen and its licensee, Johnson & Johnson, have commercialized a rHuEPO product known as Epogen®.[4] Outside the United States, Roche affiliates have manufactured and marketed a rHuEPO product known as NeoRecormon®. NeoRecormon® is one of the leading drugs used to treat anemia in Europe. Roche does not sell NeoRecormon® in the United States.

B. Roche's Novel Drug CERA

Responding to the need for improved anemia drugs and patient choice, over seven years ago, Roche embarked upon an extensive research program directed at developing superior anemia treatments. As part of that program Roche experimented with a process called "pegylation." Pegylation is a complex, highly unpredictable process that can be used to create new molecules. CERA (short for Continuous Erythropoiesis Receptor Activator) was created by Roche using a specific pegylation process.

CERA is a unique molecule that differs considerably from rHuEPO in both its chemical and biological properties. CERA is substantially more complex, and has almost twice the molecular weight and physical size of rHuEPO. CERA has a considerably longer circulating lifetime in the human body, is more soluble, and its formulation is more stable at room temperature than formulations of rHuEPO marketed by Amgen. Unlike traditional rHuEPO products, which are quickly internalized and degraded after binding to the receptors involved in stimulating red blood cell production, CERA has a greatly reduced affinity to the receptors. This reduced affinity at the receptor allows CERA to stimulate red cell production without immediate

[4] Johnson & Johnson, and its affiliates, market this product in the United States under the brand name Procrit® and in Europe under the brand name Eprex®.

degradation. CERA's distinct molecular interaction has an essential role in providing targeted, stable and sustained control of anemia.

As discussed below, to gain approval for the sale and marketing of CERA in the United States, Roche must file an Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use ("NDA" or "BLA") because CERA is a new chemical entity containing "no active moiety that [previously] has been approved by [the] FDA." 21 C.F.R. § 314.108(a) (April 1, 2005). *See also* 21 C.F.R. § 314.50 (providing requirements for an NDA).

C. The State Of Development Of CERA

As a new chemical entity, CERA must undergo the full and rigorous approval process mandated by the FDA for filing an NDA or BLA. 21 C.F.R. § 314.50. A "sponsor"[5] of a new drug must fulfill three basic FDA requirements: (1) preparation and submission of an Investigational New Drug Application ("IND"); (2) performance, with FDA approval, of a series of clinical trials on human subjects; and (3) analysis of the resulting clinical data and preparation and submission of an NDA or BLA. See Declaration of Iris Kingma-Johnson submitted together with and in support of this motion ("Kingma-Johnson Decl."), ¶¶ 4-6. Roche is CERA's sponsor in the FDA approval process. *Id.* ¶ 4.

In compliance with the FDA's requirements, CERA is currently undergoing clinical trials to evaluate its use in two separate indications: (1) treatment of anemia of chronic kidney disease; and (2) treatment of anemia in an oncology setting. *Id.* ¶ 7. As part of routine drug development there are three phases of clinical trials designated Phase 1, Phase 2 and Phase 3. 21

[5] A "sponsor" is a "person who takes responsibility for and initiates a clinical investigation" and may be an individual, pharmaceutical company or other organization. 21 C.F.R. § 312.3(b) (April 1, 2005).

C.F.R. § 312.21; Kingma-Johnson Decl. ¶ 6. Clinical testing for the two separate indications for CERA is at different phases, with clinical trials for use of CERA in chronic kidney disease patients further advanced than clinical trials for use of CERA in an oncology setting. Kingma-Johnson Decl. ¶ 7. The BLA for use of CERA in chronic kidney disease patients will be filed first. A final disposition of the chronic kidney disease BLA will almost certainly precede a disposition on a BLA for use of CERA in an oncology setting. *Id.*

With respect to the indication for the treatment of anemia of chronic kidney disease, Roche announced the successful completion of four pivotal Phase 3 clinical trials for CERA on December 16, 2005. *Id.* ¶ 9. The successful completion of these studies has been acknowledged by Roche as an important step towards filing its BLA for the use of CERA to treat renal patients, which Roche expects to file later this month. *Id.* ¶ 11. However, as is the case with any clinical trials, there is no assurance that the data generated to date will be sufficient to support the preparation and submission of a BLA filing. *Id.* ¶ 10. This cannot be determined until the laborious and time-consuming process of compiling and analyzing the data is complete. Assuming that sufficient data has been collected to file a BLA, the ensuing FDA review process does not guarantee approval and there is considerable potential for delay. *Id.* As this Court has recognized in the past, the uncertainty of the FDA approval process arises not only from its lengthy review process, but also from the FDA's inherent ability to require significant changes to an applicant's label, safety statements and manufacturing processes in order to obtain approval. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112 **(D. Mass. 1998)** (Young, C.J.) **("Not** only is FDA approval uncertain, but the process or the product itself may be altered during the interval in ways that are material to an infringement analysis.").

The uncertainty endemic to the FDA approval process has only been exacerbated by recent high profile drug safety issues, such as Merck's Vioxx® product. As recently stated by the director of the Tufts Center for the Study of Drug Development, Kenneth Kaitin: "[i]t's hard to imagine that the individual reviewers within the agency aren't more concerned about safety issues [than before] and as a result are being more cautious in their drug reviews, which is tending towards requesting more data and extension of the overall approval time." *The Pink Sheet,* Vol. 67, No. 45, Nov. 7, 2005, attached as Ex. 1 to the accompanying Declaration of Howard Suh, Esq. ("Suh Decl."), at p. 17. In fact, in 2002-2004 the average approval time for a Standard[6] new chemical entity was about 22 months, which is the longest period for approval since the 1993-1995 time frame. *Tufts Center for the Study of Drug Development, Impact Report* Vol. 7, No. 6, Nov./Dec. 2005 ("Tufts November/December 2005 Study"), attached as Suh Decl. Ex. 2, at p. 4. See also FDA CBER[7] New Drug Approval Times, *available at* http://www.fda.gov/cber/products/apprtime.htm, attached as Suh Decl. Ex. 3 (average median total approval time for standard BLAs in 2002-03 time period was approximately 25 months); FDA CDER[8] Approval Times for Priority and Standard NMEs and New BLAs Calendar Years 1993-2004, *available at* http://www.fda.gov/cder/rdmt/NMEapps93-04.htm, attached as Suh Decl. Ex. 4 (Median Total Approval Time for 2004 was 24.7 months); CBER Approval Times for Priority and Standard BLAs and Device Applications, *available at*

[6] The FDA divides New Drug Applications into those that receive Priority and those that receive Standard review. *See Tufts Center for the Study of Drug Development, Impact Report* Vol. 7, No. 6, p. 4, November/December 2005, attached to the Suh Decl. as Ex. 2. CERA has been given Standard review status.

[7] Center for Biologics Evaluation and Research.

[8] Center for Drug Evaluation and Research.

http://www.fda.gov/cber/products/apprtime2.htm, attached as Suh Declaration Ex. 5 (therapeutic biologic products including Erythropoiesis Stimulating Agents ("ESAs") such as CERA were transferred from CBER to CDER in October 2003).[9] Moreover, recent estimates place the number of drugs that fail in Phase 3 at about 50%, up from 20% ten years ago. Suh Decl. Ex. 1 at p. 18. In addition, recent reports of complications and severe anemia in certain patients taking ESAs have resulted in required changes to product information of some currently marketed ESAs and a recommendation to discontinue use of ESAs in patients who develop pure red cell aplasia (PRCA) and severe anemia. Kingma-Johnson Decl. ¶ 10. These recent findings have caused increased scrutiny of ESAs. *Id.* This could lead to longer approval times for new ESAs such as CERA.

Thus, even though Roche expects to file its BLA for CERA later this month, and even if the approval process proceeds expeditiously, there can be no certainty as to when CERA will be approved. If it takes the average approval time in recent years, CERA will not gain approval until about 22-25 months after the BLA is filed with the FDA.

D. Specific Allegations in Amgen's complaint

Amgen alleges that a Roche pharmaceutical composition called "Ro50-3821," "R744," and "Continuous Erythropoiesis Receptor Activator" either itself infringes or is made by a process that infringes Amgen's rHuEPO patents. Amgen brings a single cause of action for declaratory judgment of infringement. *Significantly, Amgen does not bring a claim for current*

[9] While the FDA Prescription Drug User Fee Act ("PDUFA") states that it is the agency's goal to complete review of 90% of new drug or biologic applications within 10 months, the actual number in recent years has been closer to 22-25 months as detailed above. *See* PDUFA Reauthorization Performance Goals and Procedures, *available at* http://www.fda.gov/oc/pdufa/PDUFAIIIGoals.html, attached as Suh Decl. Ex. 6.

patent infringement. Despite this omission, Amgen uses the present tense at times in making conclusory statements of allegedly infringing actions by Roche. For example, Amgen states that Roche is "currently importing into the United States" the allegedly infringing product, yet it is clear from the other allegations that Roche's product is not approved for sale in the U.S., and that Roche's alleged importation activities are solely for purposes of seeking such approval from the FDA. *Complaint* ¶ 18.

Moreover, Amgen's single cause of action for declaratory judgment is based on an allegation that there is an imminent threat of infringement by Roche. In an attempt to support this claim, Amgen provides a list of actions by Roche that allegedly evidence "meaningful preparations to market and sell." In essence, these actions generally include (a) *Preparing submissions for FDA approval*; (b) *Hiring staff*; (c) *Contacting potential customers*; and (d) *Building overseas manufacturing facilities. Complaint* ¶ 28. As detailed herein, although these activities may serve additional purposes, they are all either directly related to and/or necessary to obtain FDA approval.

III. ARGUMENT

A. Amgen's Complaint Should Be Dismissed as the Relevant Conduct Alleged In the Complaint Is Protected by Section 271(e)(1).

Amgen's failure to include a cause of action for current patent infringement was undoubtedly not an oversight, but an acknowledgement that *none* of Roche's current activities with CERA fall outside the protection of the § 271(e)(1) safe harbor. Nonetheless, unwilling to risk the possibility that Amgen would not be able to control the venue in which a potential future litigation with Roche would be adjudicated, Amgen filed this premature action in Massachusetts.

In its haste to do so however, Amgen has cobbled together a complaint that fails on substantive and procedural grounds.

First, 35 U.S.C. § 271(e) provides,

> (1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

The exemption under section 271(e)(1) "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2380 (2005) (emphasis in original). The limitation to "uses reasonably related" to FDA approval broadly encompasses all activities germane to compliance with FDA regulations concerning drug approval, including, among other things, preclinical studies relating to the drug's safety, efficacy, mechanism of action, pharmacokinetics, and pharmacology. *Id*. at 2381. Since "section 271 applies generally only to activities that might constitute infringement . . . defendant need not show that all of its conduct falls under the section 271(e)(1) exemption, only the [allegedly infringing acts]." *Hoechst*, 3 F. Supp. 2d at 107. Non-infringing acts (acts that do not constitute infringement under §§ 271(a) or (g)) done for other uses are irrelevant, and have no bearing on whether the alleged infringing acts fall within the uses permitted by section 271(e)(1). *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1277-78 (N.D. Cal. 1991), *aff'd* 991 F.2d 808 (Fed. Cir. 1993).

CERA has been and continues to be used in the United States in clinical trials to evaluate both the use of CERA to treat anemia of chronic kidney disease, and to treat anemia in an oncology setting. The drug is not approved for marketing or sale in the United States. Roche's actions to date have consisted entirely of the development of data related to obtaining FDA

approval for the use of CERA in the United States. All current activities involving the importation or use of CERA in the United States are directly connected with this FDA approval process and are solely for uses reasonably related to the development and submission of information to the FDA for approval for commercial marketing and sale of CERA for use in treatment of chronic kidney disease patients and to treat anemia in an oncology setting in the United States. Because all of Roche's allegedly infringing acts are protected from infringement by § 271(e)(1), Amgen does not and cannot state a claim for infringement, and its complaint should be dismissed.

Second, Amgen's complaint makes no allegation of any specific act of Roche that would constitute current infringement that falls outside the § 271(e)(1) safe harbor. At best, Amgen recites conclusory allegations that Roche is currently importing and using an allegedly infringing pharmaceutical composition called "Ro50-3821," "R744" or "Continuous Erythropoiesis Receptor Activator" in the United States. *Complaint* ¶ 18. The complaint contains no factual support or detailed allegations for this claim. Nowhere does Amgen explain why, or even allege that, the alleged conduct is not protected by the 271(e)(1) safe harbor. Notwithstanding the deferential standard of review on a motion to dismiss, the court need not accept as true unsupported assertions or mere conclusions of law. *Resolution Trust Corp. v. Driscoll*, 985 F.2d 44, 48 (1st Cir. 1993); *Papasan v. Allain*, 478 U.S. 265, 286 (1986) (a court is "not bound to accept as true a legal conclusion couched as a factual allegation").

A patentee cannot parrot the statute and escape dismissal of its complaint by merely asserting that defendant does what the statute prohibits. *Ristvedt-Johnson, Inc. v. Peltz*, No. 91 C 3273, 1991 WL 255691, at *4-*5 (N.D. Ill. Nov. 18, 1991) (complaint dismissed where plaintiff merely repeated the language of the statute, with respect to defendant's induced infringement but

failed to assert any facts to support allegation). Specific allegations of infringement must be asserted that form the basis of plaintiff's claims. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 381 F. Supp. 2d 452, 455 (D. Md. 2005). Amgen's failure to assert a cause of action for current patent infringement or provide any detail regarding specific allegations of infringement compels dismissal of its complaint pursuant to Fed. R. Civ. P. 12(b)(6).

B. Declaratory Judgment Action Is Unavailable and Inappropriate

Recognizing that none of Roche's alleged activities constitutes infringement, yet determined to file an action in Massachusetts, Amgen asks this Court to divert valuable judicial resources to a declaratory judgment action based upon hypothetical future actions of Roche. Amgen's declaratory judgment action fails to meet the case or controversy requirement of the Declaratory Judgment Act, and should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. Even if declaratory judgment jurisdiction were possible, this Court should decline to exercise jurisdiction over this action. To do otherwise undermines the safe harbor of section 271(e)(1), and unfairly rewards Amgen for filing a declaratory judgment based on improper motives.

1. This Court Does Not Have Jurisdiction to Grant Declaratory Relief Because There Is No Actual Controversy.

Under the Declaratory Judgment Act, a court does not have jurisdiction to entertain a declaratory judgment action unless it is presented with an "actual controversy." 28 U.S.C. § 2201(a); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988). To meet the controversy requirement, there must be a sufficient allegation of immediacy and reality. *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990). The Federal Circuit has found that where an alleged infringer's actions are related to the FDA approval

process, and approval is both uncertain and distant, the requirement of immediacy and reality is not satisfied, and cannot form the basis of jurisdiction for a declaratory judgment against the alleged infringer. *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1526-27 (Fed. Cir. 1992) (no declaratory judgment jurisdiction where accused device had only recently begun clinical trials, and was years away from potential FDA approval).

The allegations pled in Amgen's complaint describing Roche's activities regarding CERA do not meet these requirements of reality and immediacy. Amgen's declaratory judgment action is based on its allegation that once approved, Roche's future activities with CERA will infringe Amgen's rHuEPO patents. *Complaint* ¶ 29. Amgen seeks to support this allegation with Roche's stated intention to file for and obtain regulatory approval for CERA within the next twelve to fourteen months. *Id.* ¶ 27. Amgen further asserts that Roche has made "meaningful preparations" to market and sell its allegedly infringing product in the United States by hiring sales and management staff, contacting customers, and building manufacturing facilities overseas. *Id.* ¶ 28.

However, Amgen's arguments fly in the face of Federal Circuit precedent which has held that such activities cannot support a declaratory judgment. In *Telectronics*, 982 F.2d at 1527, the Federal Circuit affirmed the dismissal of a declaratory judgment action for infringement because all of the alleged acts of infringement related directly to the FDA approval process. As the Court reasoned, (1) defendant had not completed clinical trials; (2) at the commencement of the suit, defendant was years away from potential FDA approval; (3) defendant "was prohibited by FDA regulations from distributing sales literature and soliciting orders"; and (4) "[t]here was no certainty that the device when approved would be the same device that began clinical trials." Id.

As detailed below, these same considerations apply to Roche's current activities and compel dismissal of Amgen's declaratory judgment cause of action.

With clinical trials for treatment of anemia in cancer therapy patients ongoing, and the data from the first four Phase 3 trials for the treatment of anemia of chronic kidney disease being compiled while another two chronic kidney disease Phase 3 trials continue, Roche is currently immersed in the FDA approval process. Roche has yet to file any BLA for CERA. A BLA for use of CERA to treat anemia of chronic kidney disease is anticipated to be filed later this month, while a BLA for use of CERA to treat anemia in an oncology setting is not anticipated to be filed before some time in 2009. Kingma-Johnson Decl. ¶ 11. Even after a BLA is filed, there is no way to guarantee that any drug, including CERA, will gain FDA approval, or that the FDA will not require additional studies and/or significant changes to the applicant's label, safety statements and manufacturing processes prior to approval of a product. Roche should not be forced to divert its resources from its efforts to gain approval for its superior anemia drug to defend against Amgen's at best premature attack.

Moreover, the "meaningful preparation" activities alleged by Amgen, *Complaint* ¶ 28, are either not infringing activities or are necessary for work needed to gain FDA approval and thus protected by § 271(e). The fact that Roche may be doing some of these things now is not surprising, and has no impact on the fact that marketing and sales of CERA cannot occur unless and until CERA receives FDA approval, an event that will take about 22 to 25 months from the future filing of the BLA if CERA follows the average time for approval of recent years. *See* Suh Decl. Ex. 2; *Id*. Ex. 4 (Median Total Approval Time for 2004 was 24.7 months).

Some of the following allegations from Amgen's complaint are simply not correct, but even taking each one as correct at face value, these activities are not inconsistent with, and in

fact are often part of, the effort to file a BLA and gain approval for a new drug. For example, Complaint paragraphs 28.a., *"Completing its collection of data from its PEG-EPO phase III clinical trials to file its Biologics License Application with the FDA,"* and 28.b., *"Preparing to file or filing an application with FDA for regulatory approval to market and sell PEG-EPO in the United States"* on their face are actions taken as part of the FDA approval process.

Complaint paragraph 28.c. alleges *"Hiring key management, support, and sales personnel."* Many of these personnel are useful and needed to assist in arranging for and conducting pre-clinical and clinical trials of a scale necessary to satisfy the requirements of the FDA approval process and ongoing trials after approval. 21 C.F.R. § 601.2. For example, Phase 3 clinical trials alone require several hundred to several thousand patients. 21 C.F.R. § 312.21(c). Without appropriate personnel, managing these trials and collecting this data would be impossible. In addition, some of these personnel are useful and needed to develop marketing and sales strategies for use if and when Roche gains approval to market and sell CERA. Nonetheless, Roche is prohibited from marketing or selling CERA unless and until it receives FDA approval.

Complaint paragraph 28.e., *"Contacting . . . large dialysis organizations"* is necessary because these are a primary source of patients who can participate in clinical trials to generate the data needed for approval. Similarly *"solicit[ing] interest"* (not sales) is essential to encourage patients and providers to participate in the trials. Until FDA approval, there can be no sales of CERA.

Finally, Complaint paragraph 28.f., *"Completing construction and commencing operations of a new facility in Penzberg Germany to manufacture"* the accused product for importation into the United States, is a necessary part of the FDA approval process because the

drug sponsor must present detailed information about the facility in which the drug will be manufactured, and the facility must pass an inspection to ensure compliance with the requirements of all applicable regulations. 21 C.F.R. § 601.20. *See Chartex Int'l PLC v. M.D. Personal Prods. Corp.*, 5 F.3d 1505, 1993 WL 306169, at *3 (Fed. Cir. Aug. 12, 1993) ("Making arrangements to have a device manufactured overseas or making arrangements to have it imported into a foreign country" is not an infringing act and does not obviate protection under §271(e)(1)). *See also Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 938-39 (N.D. Ill. 1995) (finding that defendant's conduct was not infringement because the accused product was still under consideration by the FDA and approval was not guaranteed). Indeed, none of these steps of "meaningful preparation" are acts that can constitute infringement under any circumstance. *See Merck*, 125 S. Ct. at 2380 (Court reasoned that federal law provided "a wide berth for the use of patented drugs in activities related to the federal regulatory process" and that "[t]his necessarily includes preclinical studies").

By Amgen's own allegation, Roche has yet to file a BLA and projected regulatory approval to market and sell CERA is at least twelve to fourteen months after filing. *Complaint* ¶27. In fact, Amgen itself contends that no allegedly infringing activity will occur until "regulatory approval in the United States" is obtained. *See Complaint* ¶28. b., c., and e. Arguments that § 271(e)(1) is a narrow, limited exception that does not shield the alleged "meaningful preparations" miss the point. Section 271(e)(1)'s terms need only apply to acts that would otherwise constitute infringement. *Hoechst*, 3 F. Supp. 2d at 107.

Therefore, under these circumstances, there is no jurisdiction to hear a declaratory judgment action concerning allegations of possible sales that Amgen contends only will occur upon FDA approval. *Telectronics*, 982 F.2d at 1527; *Lang*, 895 F.2d at 764 (no actual

controversy because the nine-month period between initiation of the lawsuit and completion of the allegedly infringing hull design was too remote); *Abbott Labs.*, 934 F. Supp. at 937-38 (declaratory judgment action dismissed where defendant may receive FDA approval to sell accused drug three months from date complaint filed); *compare Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997) (proper to consider declaratory judgment action where there was "imminent FDA approval and actual threats of future infringement").

2. If Declaratory Judgment Jurisdiction Exists, the Court Should Refrain From Exercising That Jurisdiction.

Even if the Court finds that an actual case or controversy exists, "the exercise of a court's jurisdiction over a declaratory judgment action is discretionary." *Telectronics*, 982 F.2d at 1526. *See also Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991) (same). Where jurisdiction exists over a declaratory judgment action, the Court always has the option of declining to exercise that jurisdiction. *EMC Corp. v. Roland*, 916 F. Supp. 51, 53 (D. Mass. 1996) (O'Toole, J.) ("Even when a court properly has jurisdiction over a declaratory judgment action, however, the court is not required to exercise that jurisdiction."). The circumstances of this case strongly suggest that this Court should use its discretion to dismiss this case.

First, to allow this case to proceed completely undermines the policy endorsed by Congress in enacting 35 U.S.C. § 271(e)(1). If a patentee can base a declaratory judgment action solely on the fact that defendant has sought FDA approval for its product and undertaken actions to facilitate that approval, then § 271(e)(1) is useless in relieving the defendant of the type of "expensive, resource-draining, and personnel-distracting litigation" that § 271(e)(1) was designed to avoid. *Intermedics*, 775 F. Supp. at 1290. This Court recognized this policy when it stated that such declaratory judgment actions "may run afoul of the Congressional policy

underlying the section 271(e)(1) exemption." *Hoechst*, 3 F. Supp. 2d at 112. Such a declaratory action "could easily become a tool of harassment and intimidation for use in discouraging early efforts at competition." *Id.* at 113. Indeed, when asked recently about Roche's plans to file in 2006 for U.S. approval to market CERA for anemia for kidney disease, Amgen chief executive Kevin Sharer replied, "We have to stop them altogether." *Amgen's 'Strategic Intention' is to Acquire - CEO*, Reuters, Mar. 1, 2006, attached as Suh Decl, Ex. 7.

Recently, Ortho Biotech Products, L.P. ("Ortho") filed a baseless motion to intervene in this litigation. In its proposed complaint, Ortho seeks to not only join the suit as brought by Amgen, but tries to expand the scope of the litigation by requesting damages despite the fact that Roche has not even filed a BLA for CERA, and any approval to sell or market CERA would take at least 12-14 months according to Amgen's and Ortho's proposed complaints. The merits of Ortho's motion are discussed in Roche's opposition to Ortho's Motion to Intervene, filed concurrently herewith. However, this attempt by Ortho to join this litigation and expand its scope to include damages, together with the original complaint filed by Amgen, are exactly the type of "expensive, resource-draining, and personnel-distracting litigation" that § 271(e)(1) was designed to avoid. *Intermedics*, 775 F. Supp. at 1290. Allowing Amgen and Ortho to maintain, and even expand, this lawsuit at this time provides these parties "a tool of harassment and intimidation for use in discouraging early efforts at competition." *Hoechst*, 3 F. Supp. 2d at 113.

In enacting the safe harbor, Congress intended that while a company was proceeding through the long FDA approval process, the company would take some steps to prepare for sale of a product if and when FDA approval were granted. *Telectronics*, 982 F.2d at 1525 ("Congress must have intended to allow competitors to be in a position to market their products as soon as it was legally permissible."). To find that the allegedly infringing acts are exempt from a current

assertion of infringement because they are acts that fall within the safe harbor of § 271(e)(1), while allowing a declaratory judgment action based on the current, unapproved product undermines the purpose of the safe harbor. *See Intermedics*, 1993 WL 87405, at *4. ("To permit [defendant] to be protected from direct suit for infringement and yet allow the same activities to be subject to suit in a declaratory judgment action would be nonsensical.").

Moreover, the timing and venue chosen by Amgen for this suit reveal that its decision to file this case was not induced by the merits of this action but by anticompetitive motives and forum shopping. Amgen chose to file at the commencement of the American Society of Nephrology Annual Meeting held in Philadelphia on November 8-13, where Roche was rumored to announce positive results of its Phase 3 renal trials for CERA. Undoubtedly, Amgen intended its November 9th press release to alert the public to the fact that Amgen would not permit Roche to bring CERA to the U.S. market. Amgen's desire to overshadow Roche's ongoing clinical success is obvious. Apparently, Amgen was more concerned about impressing its investors than with the legalities of needing an actual controversy sufficient to bring a declaratory judgment action at this time.

This case also represents blatant forum shopping by Amgen. The case was filed in this Court despite the fact that Roche has no offices, employees, or significant presence within Massachusetts. Amgen apparently sought this forum based solely on prior successful litigation results involving the same patents here, not because of any nexus between the allegations of the complaint and this jurisdiction. The fact that a declaratory judgment action at this time would undermine the purpose of the safe harbor of 35 U.S.C. § 271(e)(1), combined with Amgen's improper motives and blatant forum-shopping, should lead this Court to exercise its discretion and decline to exercise jurisdiction in this matter.

IV. REQUEST FOR ORAL ARGUMENT

Roche believes oral argument will assist the Court in deciding this motion, and wishes to be heard.

V. CONCLUSION

For all the foregoing reasons, this Court should dismiss Amgen's complaint in its entirety for failure to state a claim upon which relief may be granted and lack of subject matter jurisdiction. In the alternative, this Court should decline jurisdiction over Amgen's claims for declaratory judgment of infringement based on alleged future actions of Roche, and dismiss this complaint.

DATED: Boston, Massachusetts
April 11, 2006

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

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I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Julia Huston

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